TITLE OF INVENTION

Applicant:- Dr. Kartikeya Pranjivan Pathak

Citizen of India

Resident at- 260/5, "Harinav" ,

Navrangpura, Near Panjabi Hall,

Ahmedabad- 380009, India.

"The Renew Compression Screw", a basic bone implant device for external fixator with improved and renewable stability, also serving as a lag screw with renewable compression, creating improved and durable bio-mechanical conditions for bone union.

CROSS- REFERENCE TO RELATED APPLICATIONS

" Not Applicable"

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

" Not Applicable "

REFERENCE TO A MICROFICHE APPENDIX

" Not Applicable "

BACKGROUND OF THE INVENTION

This relates to the field of Orthopedics and Trauma, human, or veterinary. It may also have applications in non-living mechanical materials.

Bone is living tissue. Bone fragments and surfaces can unite by biological activity over a length of time, given proper conditions to favor it. During this biological process of healing, the fragments have to be held together continuously by various means, to achieve a finally acceptable shape and length of the bone without deformity ,and of sufficient strength to restore function to the part.

The biological process is favored by the following measures.

- Immobilization of the fragments or surfaces attempting union.
- Compression of the surfaces to increase the rigidity of immobilization, and also promoting the biological process of direct union without excessive callus formation.
- To relieve stress and recurrent injury to the soft-tissues and neuro-circulatory mechanisms by the immobilization.
- Immobilizing only the healing parts, and to encourage movement and activity of un-injured parts.

This has been attempted by the following methods.

A. Continuous traction.

B. External casts of Plaster of Paris, other casting material and braces.

C. Internal fixation.

D. External fixation.

E. Combined methods of fixation.

F. This refers to the properties of the claimed invention.

A. Continuous traction:-

This can restore the length of the limb, and further measures can correct deformities like rotation and angulation to some extent.

The following problems of this method seldom make it the preferred treatment.

- It is difficult to maintain the traction force continuously even with very frequent attention.
- Patient cooperation is difficult to achieve.
- Due to intermittent loss of traction force, mal-union may occur. Distraction and movement of fragments may cause delay or failure of union.
- Circulatory problems can occur in the distal limb.
- Wounds in the traction surface will not allow such a treatment.

B. External casts of Plaster of Paris, other casting material and braces.

The following problems are associated with them.

- The immobilization is not rigid enough when it is critically essential.
- Encircling of the part causes sweating and discomfort in hot climates.

Pressure sores can occur at pressure points, or due to insertion of hard objects by patient for scratching. Bugs can get in.

- Swelling of part within the cast can cause tightness and loss of circulation.
- Loosening of cast occurs due to loss of swelling of part, or due to moisture reducing the thickness of the padding, resulting in loss of reduction.
- There is no access to any wounds inside which may need attention, except by cutting out windows or leaving the cast incomplete, which may jeopardize the immobilization, and fracture reduction.
- Uninvolved parts also get immobilized, a setback to recovery.

Due to these factors it can suffice only when rigid immobilization is not critically important, and usually in the absence of complicating factors of wounds and circulation.

C. Internal fixation :-

This may be applied along the side of a bone in the form of a plate and screws of the preferred design. It allows accurate reduction when this is most desirable, a bone graft can be added, and lag screws may be added when feasible, for inter-fragmentary compression. Sliding devices can be added to passively close any gaps arising later.

Disadvantages are as under.

- Large exposures are required with relatively greater damage to the soft-tissues and bone circulation. Meticulous technique may minimize this, yet exposure is larger.
- Compression once applied at operation, wears off within hours depending on the quality of bone. There is no possibility of renewing this compression once the wound is

closed over the device. It is not acceptable to re-anaesthetize and re-expose the device repeatedly to re- tighten the screws.

- Newer minimally invasive methods are performed through smaller incisions but in order to place the plate directly on bone, the periostium and muscles have to be stripped blindly. Even so, the plate is always unavoidably placed over some soft-tissues which melt away by the pressure and loosen the plate within hours. Loss of torque of screws is unfavorable to bone biology.
- Plates are seldom favored in compound fractures.
- Fracture haematoma gets dispersed.

Internal fixation may be applied inside the medullary canal of bone in the form of nails, pins and wires.

In closed nailings the fracture haematoma is preserved

The disadvantages are as under.

- It is generally not applicable to children, due to growth plates at the ends of bones.
- It invades and occupies the bone from end to end, with the possibility of spreading infection.
- It is not stable to rotational forces, and interlocking methods are not available for all situations.
- In open nailings , the fracture haematoma gets dispersed.

D. External fixation:-

This is most ideally suited for open injuries of bone. The commonly used basic bone implant for the external fixator is the Schanz screw which can be inserted at a safe

distance from the open wounds and fracture ends.

- Access to the wounds for frequent attention is easy.
- There is no aggravation of injury to bone or soft-tissue.
- Safe corridor entries of screws prevent injury to neuro-vascular structures.
- In transverse fracture patterns, some compression can be applied along the axis of the bone

The following limitations remain:-

- The basic implant e.g. the Schanz screw has a tendency to loosen in bone, leading to instability, and tendency to infection. Radial stressing of the implant in bone improves the stability, by the technique of inserting a larger diameter screw in a suitably smaller diameter drill-hole.
- The preload is only in one mode, viz. Radial.
- After loosening, there is no way of regaining any degree of stability in the same position, before the onset of infection. If the loose screw had been initially placed in the ideal site, then any next site for re-positioning the screw will be less than ideal.
- There is no lag screw effect of a Schanz screw, to exert inter-fragmentary compression. Inter-fragment compression greatly enhances the stability, as well as the biological process of union. Fragments can at the most be splinted across, but not drawn together and compressed as in the lag-screw mode, by the conventional Schanz screw.

E. Combined methods of fixation:-

When any one method is inadequate to neutralize all the forces of muscular pull and gravity, another method is added onto the first. For example, in " mini- internal fixation "

methods, one or two lag screws used to hold together some fragments, are supplemented by an external fixator construct, or by traction.

Even with such a supplementation, the lag screws can fail, because by the blind stab-hole technique, there is always some interposition of soft-tissue between the screw-head and the bone surface. This soft tissue quickly undergoes pressure necrosis to loosen the compression by loss of torque. The only residual control then is the external fixator, which may not be adequate for joint fragments. The compression once lost cannot be regained.

E. The claimed invention:-

This invention aims to preserve and augment the function of the primary bone implant of the external fixator. This is by a design which adds the effect of an axial preload on the thread in the bone, to the older technique of radially preloading the implant. This has an additional effect on the stability and durability of the screw. The third element of stability is the surface preload of the screw-head on the bone surface. This is independent of the function of the head in exerting axial preload torque on the thread within the bone. These stabilizing qualities are also renewable, because the screw can be again tightened after the first insertion.

Further, there is the introduction of the "lag-screw" function in the same basic implant of external fixator which is a totally new concept.

There is also the capability of renewed and prolonged inter-fragmentary compression by means of subsequent turning of the screw from outside, which is a new and major advantage to the biology of bone healing.

The major drawback of the conventional Schanz screw of loosening is corrected to a significant extent, by this triple mechanism.

All positive features of the older implant are retained.

This device can be used to supplement minimally invasive plate oesteosysthesis with double advantage. The screw torque can be renewed to keep the plate firmly seated on bone. The same screws form a construct outside and prevent failure of implanted plate.

~~BRIEF SUMMARY OF THE INVENTION~~

The general idea and the objective of the claimed invention is to overcome some shortcomings of older methods, and make it more versatile.

The claimed invention combines the beneficial aspects of internal as well as external fixation. The older Schanz screw never had any lag-screw function. Even when used across any fracture line, it would merely splint the fracture but could never compress the fragments. Thus the older screw was mainly for gripping the main fragments for participation in the construct. Lag screw mode was entirely a function of the internally fixed screw, and not the Schanz screw.

As a member of the external fixator class, it has multiple stabilizing factors beyond the present designs; radial preload, axial preload on thread, and surface preload of head on the bone surface. It is designed for increased primary stability and durability and is capable of being re-tightened in the same site, to preserve stability.

It has no disadvantages of any kind whatsoever, compared to the available fixator screw implants, and permits wound access, is applied through minimal incisions, does not

damage soft-tissue as in the open reduction and internal fixation methods, does not invade the medullary canal length-wise, and is applicable to children.

As a member of the internal fixation class of implants, it not only holds but compresses the fragments in the lag- screw mode, and also overcomes the problem of invariable loosening soon after first application. Due to its projection outside the skin, it can be re-tightened as required to renew the compression torque, and simultaneously participate in the external construct to augment stability.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Drawing 1. It shows the essential features of the invention, which is a rod-like implant with the following components.

a. The tip:- This is meant for implantation, and may be self-tapping or not. The device in the drawing is cannulated, to permit a guide-wire technique. However, it may be solid in other samples of the device.

b. The thread:- The drawing shows a partly threaded device, which is intended for use as a lag screw. When intended as a basic implant, or when not intended for compression, the thread extends to the screw- head.

c. The smooth shaft of screw section:- This is absent in a fully threaded device. The distance between the partial thread and the head is variable to suit the length of the sliding drill-hole.

d. The screw head:- This is may be shaped hemispherical like the conventional screw – head, discoid, reverse conical, spherical or any other shape so long as it can rest on the bone surface and be driven tight against it. It may be integrated

into the implant body or may be loosely or separately fitted.

e. The external drive-shaft:- This extends from the screw- head to the exterior end of the device, and may be of any suitable diameter.

f. The grip:- This outer end of the device may be identical with the rod. It may be milled, or flattened to an isosceles triangle for gripping, or a quick-coupling type.

All the dimensions are variable; the diameters of the canulation, the outer thread, the core, the screw-head, the external rod; as also the lengths of the thread, the tip to head distance, and the overall length.

Drawing 2.

A. This shows the conventional radial preload, by driving a screw into a smaller diameter drill-hole. The view is a cross- section.

B. This shows the axial preload on the thread along the axis of the claimed invention, upon the thread in the bone. The implant is axially tensioned. There is radial preload also.

C. This shows the surface preload of the screw- head upon the surface of the bone, independent of the axial preload. The fixed flat under – surface is of a limited contact type and used at right angles to bone surface. At any other angle, the under surface is spherical, a washer may be added on a thin cortex. There is also radial preload.

Drawing 3. This shows a common variety of hip fracture, treated by internal fixation with a frequently used two- piece device. At the end of fixation, compression is applied between the fracture surfaces, with another smaller fine threaded screw, which draws the hip-screw into the plate barrel. After the wound is closed over the device, the compression wears off. Any subsequent gap due to bone resorption may get closed by

sliding of the screw within the barrel. If this passive movement fails to occur, the persistent gap causes failure of union and implant.

Drawing 4. The same fracture is treated with an external fixator. The fragments are splinted over the upper two Schanz screws, but no active compression is present. Passive sliding cannot occur, unless the screws are loose in the clamps, making the construct unstable. The lower two screws are the basic implants of the fixator, which can exert preload only in the radial direction, if driven in suitably smaller drill-holes. There is no element in the design for the addition of other preload factors, or for renewability of preloads. Axial preload is not renewable.

Drawing 5. The claimed invention is used to create an external fixation construct. The upper two screws actively compress the fracture surfaces by the lag-screw effect. The same screws simultaneously participate in the external construct. Any subsequent loosening can be overcome by re-tightening the lag-screws to regain the compression.

The lower two screws are the basic implants for completion of the construct. In addition to a radial preload by technique, the head exerts surface preload on the bone by implant design, adding to the lateral stability. In addition, there is an axial preload along the screw thread on tightening the screw. The latter two effects are incorporated in the design of the invention, and are renewable by re - tightening from without. Axial preload is not renewable but it is protected by the two newer forces.

Drawing 6. The claimed device plays an invaluable role in the management of an intra-articular fracture. The articular fragments are not only splinted but actively

compressed by the claimed invention. This compression by the lag-screw principle is also renewable. The same device is incorporated in the external construct, to hold the articular fragments reduced to the rest of the bone. The articular screws need not be in the same plane as shown in the drawing, and can be creatively inter-connected to other construct components.

DETAILED DESCRIPTION OF THE INVENTION

The invention distinguishes itself from older internal fixation screws in lag mode by the following qualities.

The conventional lag screw is imbedded in the tissues after the wound is closed over it, whereas the invention projects outside the skin surface.

The conventional screw in lag-screw mode cannot be accessed repeatedly for refreshing the compression between fragments. This would require repeated anaesthesia and reopening of the wound. The invention being outside the skin can be loosened in the clamp, turned tighter on the bone, and secured again to the clamp.

The invention distinguishes itself from the conventional basic implant of the external fixator in the following features.

The conventional implant can be inserted with a radial preload to enhance its stability, by driving it through a suitably smaller drill-hole. The radial preload can be applied in this invention also. However, in addition to this radial preload, the principle incorporated in its design adds two other stabilizing factors. One is an axial preload along the thread. The other is the surface preload of the head on the bone surface, which works at an angle of 90 degrees to the radial preload. These three combined effects gives the

invention better immediate and more durable stability without loosening.

The conventional Schanz screw implant once loosened, stays loose and encourages sepsis. Due to the presence of the intercalated head in the invention, it is possible to renew its stability by turning it tighter, periodically. Stability of implant discourages sepsis. Though the radial preload is not renewable, when supplemented by the other two preloads, it lasts longer. Even if radial preload is abolished with time, the other two are renewable.

The conventional Schanz screw was never intended for the lag-screw mode. It was primarily for getting control over the main two fragments of bone in a fracture by engaging them. After this the fragments could be manipulated into reduction by moving the fragments about with the leverage gained, and fixed. If ever inserted across a fracture line, it could only splint the fragments across, with or without gap. Passive sliding is prevented by the fixator clamps.

The claimed invention is not only capable of being inserted in the lag-screw mode, but has the unique quality of allowing renewal of the compression from out-side. This is in addition to its function as a basic implant.

The tip of the screw is self-tapping where the torque required is not excessive. In hard bone , more lasting stability is gained by using a bone-tap prior to screw insertion. Short threaded screws in lag mode, and those which may need removal and replacement, are not self-tapping.

The cannulated pattern can be very helpful for intra-articular fragments, by allowing a guide-wire technique.

The length of the thread is short when intended for the lag-screw mode. The thread can then be kept out of the fracture line at the end of tightening.

For the basic implant mode, the screw is fully threaded, to encourage broader contact area for axial preload on the thread.

For fixation of intra-articular comminution, a fully threaded screw is chosen to prevent the articular surface from getting narrowed.

The ratio between the outer diameter of the screw and the core diameter is generally larger in cancellous bone than in cortical bone. The pitch of the thread is higher for cortical bone.

If the partially threaded device is used, the smooth screw-shaft is of sufficient length and proper diameter to clear the gliding hole in the near fragment.

If intended as a renewable compression lag-screw, the thread length selected will be such that the thread does not cross the fracture line, at the end of tightening.

The presence of a shaft from the thread to the head is only for gliding of the screw in the near fragment; for compression without catching in that fragment, in the lag-screw mode. Radial preload is still applicable.

The most functional part of the invention is the intercalated screw-head, its shape and position, which adds to the meaning and alters the functions of other components of the device.

The head, which is intercalated between the inner and outer tips of the device may be fixed to the rod , or may be mobile. It may be hemispherical on the deeper side like a conventional screw-head, spherical, or discoid or any other shape that may suit its

purpose of exerting the intended pressure on the bone surface. The discoid head may have a blunt serrated deeper surface to exert limited contact. There may be an in-built washer under the head, which distributes pressure over a wider area over bone surface.

The external drive-shaft is an extension of the inner screw, to give it the simultaneous functions of participation in an external construct, and of renewing the compression torque.

The outer grip end can be, by the preference of the user, either milled or quick coupling or triangulated.

The overall size of the device can be made to suit the size of the bone, the size of fragments being dealt with, and the depth of the bone from skin.

The device being an implant shall be manufactured out of an inert implantable material, having other suitable physical attributes.